



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,985	02/09/2004	Robert A. Rabiner	20563/2422	9583

26161 7590 05/18/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

HORWAT, JENNIFER A

ART UNIT	PAPER NUMBER
----------	--------------

3768

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/774,985

Applicant(s)

RABINER ET AL.

Examiner

Jennifer Horwat

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-27, 29-32 and 64-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-27, 29-32, and 64-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/13/06 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, motivation for each combination was provided in the previous Office Action and is repeated below. A variety of reasons for modifying and altering electrical and medical devices are well known in the art and such motivations are well known to those of ordinary skill in the medical device art.

Claim Objections

2. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is dependent on

later claim 29. It appears the claim was intended to be dependent on claim 19 instead of 29 and was interpreted as such for the purposes of examination.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4, 6, 7, 9-11, 17, 19-22, 25, 26, 32, 64, 65, 66, 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai, et al (US 2003/0045887). Wuchinich discloses an ultrasonic medical device that creates torsional vibration (figure 4, element 40), which discloses all of the limitations of the above mentioned claims. The probe comprises a proximal end coupled to a transducer (figure 1, element 1), a distal end, with a longitudinal axis between (figure 4), with an energy source engaged to the transducer producing ultrasonic energy (figure 1, elements 1 and 15). Torsional vibration, which by definition rotates and counter-rotates the ultrasonic probe, propagates the length of the probe through the resonator resulting in a plurality of nodes (paragraph 12), which inherently result in a plurality of anti-nodes at half the distance between any two nodes. In the embodiment shown in figure 3, the longitudinal axis of the probe has a radially asymmetric cross section (figure 3, element 41). It is also possible for the axis to have an approximately rectangular cross section (paragraph 70) or have longitudinal grooves, which create a plurality of "flutes", or projections, extending along the length of the probe (paragraph 10). Additionally, the diameter of the probe can be tapered or varied from the proximal end to the distal end

of the probe (figure 4). Wuchinich, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose operating at the resonant frequency of the transducer. Sakurai also discloses an ultrasonic probe capable of torsional vibration and teaches that "resonance-point tracking" is possible in order to set the resonance frequency to the frequency of the vibration oscillator (paragraph 77). Additionally, the elongated probe of the ultrasound device has an approximately circular cross section (figure 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich with the teachings of Sakurai to increase the efficiency of the device.

5. Claims 5 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai as applied to claims 4 and 19, respectively, above, and further in view of Rabiner, et al (US 2002/0029054). Wuchinich in view of Sakurai, as discussed above, substantially discloses the invention as claimed, however does not explicitly teach that the ultrasonic probe can be used to ablate biological material along the portion of the longitudinal axis comprising the radially asymmetric cross section. Rabiner teaches that it is advantageous to use ultrasonic vibration along the longitudinal axis of an ultrasonic probe to destroy tissue along the length of the probe (paragraph 26) using cavitation in order to be less traumatic to surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai in light of the teachings of the reference by Rabiner to provide decreased procedure time and less residual tissue damage (paragraph 26).

Art Unit: 3768

6. Claims 8, 12, 14-16, 24, 27, 29-31, 67, and 70 rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai as applied to claims 1, 19, and 64 above, and further in view of Fenton (US 2003/0212331). Wuchinich in view of Sakurai, as discussed above, substantially discloses the invention as claimed, however fails to disclose the capability for flexibility of the probe and fails to explicitly disclose the operating frequency range of the device. Fenton also discloses an ultrasonic device capable of torsional vibration, which states that ultrasonic surgical instruments typically operate in the range of 20 to 100 kHz (paragraph 4). In addition, the vibration element of the probe disclosed in the reference by Fenton is "formed of a flexible, compliant material" which may "have a substantially curvilinear configuration" (paragraph 19). In another embodiment the probe has a substantially uniform cross section (figure 2A). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai in light of the teachings of Fenton as flexibility and a curved shape in the probe allow the probe to reach a greater number of areas minimally invasively.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wuchinich in view of Sakurai as applied to claim 1 above, and further in view of Jones (US 6433464). Wuchinich in view of Sakurai, as discussed above, substantially discloses the invention as claimed, however fails to teach that the device may be disposable. Jones discloses a device for dissolving and removing unwanted biologic materials using acoustic waves and teaches one advantage of the device is that it is optionally disposable (col 18, lines 59-67). It would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the device disclosed by Wuchinich in view of Sakurai with the teachings of Jones in order to make the probe disposable in order to provide a device that is more convenient to use and does not require cleaning or sterilization.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone

Art Unit: 3768

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah
5/12/06


ELENI MANTIS-MERCADER
PRIMARY EXAMINER